

REMARKS

Claims 22-42 are pending in the current application. Claims 32-42 were withdrawn from consideration as being drawn to the non-elected invention and claim 31 was cancelled by way of the amendment submitted with the request for continued examination filed on November 7, 2003. By way of the present Amendment, Applicants have amended claim 22 have and added new claims 43-47. Therefore, claims 22-30 and 43-47 are presently under examination.

Objection to the Specification

The Examiner has objected to the specification, and particularly, to the Brief Description of the Tables and Figures, because Figure 2 is referred to as “Fig. 2” instead of “Fig. 2A-2D.”

Applicants have hereby amended the specification to recite “Figs. 2A-2D” in the Brief Description of the Tables and Figures, at line 26 on page 6 of the specification. Accordingly, Applicants respectfully submit that the Examiner’s objection has been overcome.

Objections to the Oath/Declaration

The Examiner objected to the Oath because the Oath “incorrectly lists the filing date of PCT/US00/24244” as October 18, 1999. As set forth by Applicants in the Amendment submitted with the RCE filed on November 12, 2003, Applicants intend to submit a new Oath listing the application number and filing date of the present application and properly claiming priority to PCT/AU99/00897, but not claiming priority to PCT/US00/24244.

Applicants wish to bring to the Examiner’s attention once again that the as-filed Oath contains an inadvertent typographical error, which error lists “PCT/US00/24244” as a priority document. Applicants note that the present application does not claim the priority of PCT/US00/24244, and that the inadvertent typographical error appears to be based on a mistaken substitution of the publication number of a priority document for the instant application. Specifically, Applicants direct the Examiner’s attention to the first page of the Utility Patent Application Transmittal form submitted with the present application on April 20, 2001, which transmittal form properly claims the priority of International Application No. PCT/AU99/00897.

The **publication number** for the published priority document – WO00/24244 – appears to have been mistakenly read as the “application number” during the preparation of the as-filed Oath. Accordingly, when Applicants prepare a new Oath as described above, the incorrect reference will be deleted from the Oath.

Priority Documents

The Examiner has requested that a certified copy of PCT/US00/24244 be submitted to the Office in order to receive priority of that application.

As Applicants have set forth above in response to the Examiner’s objection to the Oath/Declaration, Applicants do not claim priority of PCT/US00/24244 in the present application. Rather, Applicants claim priority to PCT/AU99/00897, filed October 18, 1999, which claims priority to Australian application PP 6646, filed October 22, 1998. Therefore, Applicants respectfully submit that it is not necessary to submit a certified copy of PCT/US00/24244, as they do not claim priority to PCT/US00/24244.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claim 25 under 35 U.S.C. § 112, first paragraph, as containing new matter. Specifically, it is the Examiner’s view that the language “high molecular weight DNA being obtainable by cesium chloride fractionation” is not explicitly found in the specification and, therefore, constitutes new matter. Applicants respectfully traverse the Examiner’s rejection for the following reasons.

Applicants respectfully submit that claim 25, as previously amended, does not contain new matter. Applicants direct the Examiner’s attention to lines 29-31 on page 7 of the specification, which reads, “A preferred method of genomic DNA isolation may be found in Weining and Langridge, 1991, Theor. Appl. Genet. 82:209, which is herein incorporated by reference.”

MPEP 608.01(p)(I)(A) provides, in relevant part:

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications however, hyperlinks

and/or other forms of browser executable code cannot be incorporated by reference. See MPEP § 608.01. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art. (emphasis added).

Applicants respectfully submit that the Weining and Langridge reference was properly incorporated by reference, as it was incorporated by reference in order to illustrate one aspect of the state of the art of DNA isolation at the time of filing of the present application, namely, the use of cesium chloride fractionation to isolate high-molecular weight genomic DNA from a plant. As would have been understood by the skilled artisan at the time of filing of the present application, cesium chloride fractionation functions by separating DNA based on the size of the DNA in a composition. At the time of filing of the present application, it was well within the ability of the skilled artisan to identify the high molecular weight and the low molecular weight DNA fractions within a cesium chloride gradient.

The Weining and Langridge reference, a copy of which is provided herewith for the Examiner's convenience, describes in detail a method of DNA isolation (see page 210, second column of reference) using cesium chloride fractionation. Applicants respectfully submit that they properly and particularly directed the reader's attention to the Weining and Langridge reference for the purpose of illustrating the state of the art with respect to the isolation of high-molecular weight fraction genomic DNA using cesium chloride fractionation. Therefore, Applicants submit that the proper incorporation by reference of the Weining and Langridge reference satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

Thus, it is clear that one skilled in the art, armed with the teachings set forth in the specification as filed, including the Weining and Langridge reference, which was properly incorporated into the present application by reference, would understand what is meant by the term "high molecular weight DNA being obtainable by cesium chloride fractionation" as recited in claim 25. Further, Applicants respectfully submit that it has been demonstrated herein that Applicants were indeed "in possession" of the claimed invention at the time of filing, within the requirements of 35 U.S.C. § 112, first paragraph, in view of MPEP 608.01(p)(I)(A) as set forth, in part, above. Accordingly, Applicants respectfully submit that claim 25 does not contain "new matter" and this rejection should be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 22-25, 27, 28, and 30 under 35 U.S.C. § 103(a) as being unpatentable over Turbin et al. (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203). Specifically, it is the Examiner's view that it would have been within the scope of one of ordinary skill in the art to modify the method of Turbin et al. and to use the microprojectile bombardment method taught by Christou to deliver non-vector DNA to a recipient plant. Applicants respectfully disagree for the following reasons.

Applicants have herein amended claim 22, from which claims 23-25, 27, 28 and 30 depend. As amended, claim 22 recites an additional method step (c), so that now the claimed method requires "selecting at least one transgenic plant from step (b), wherein said transgenic plant has a genome comprising a nucleic acid that corresponds to 0.01% to 10% of a nucleic acid genome of said donor plant." Support for this amendment can be found in the specification from line 18 on page 11 through line 32 on page 12. Applicants note that the lower limit of 0.01% corresponds to approximately 3-5 genes. The skilled artisan, when armed with the disclosure of the present application, and in particular, the enabling disclosure on pages 11 and 12 of the specification, would know how to conduct such genomic integration, as well as the calculations and determinations of the approximate number of donor genes integrated into a recipient plant genome.

Applicants have also added new claims 43-47, which claims 43-47 all ultimately depend from amended claim 22. Claims 43-45 are drawn to progressively narrower ranges of introgression, and claims 46 and 47 are drawn to methods wherein the transferred DNA comprises a plurality of genetic markers, including Amplified Fragment Length Polymorphism (AFLP) markers. Support for this amendment can be found in the specification from line 18 on page 11 through line 32 on page 12. Insofar as the Examiner's rejection under 35 U.S.C. § 103(a) applies to newly added claims 43-47, Applicants respectfully submit that the arguments set forth below in response to the Examiner's rejection of claims 22-25, 27, 28, and 30 apply with equal force.

In order for a rejection under 35 U.S.C. § 103(a) to be proper, the Examiner must establish a *prima facie* case of obviousness. More specifically, it must be shown that there is some suggestion or motivation to combine the cited references, that the prior art provides one of ordinary skill in the art with a reasonable expectation of success, and that the combination of the art teaches or suggests each and every element of the rejected claims.

The three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

None of these criteria have been met here.

Neither the Turbin nor the Christou reference teach or suggest all of the claim limitations of amended claim 22 (and, therefore, claims 23-25, 27, 28 and 30, which all ultimately depend from claim 22). That is, neither the Turbin nor the Christou reference teach or suggest the step of selecting recipient transgenic plants that have an equivalent of 0.01% to 10% of a donor plant genome incorporated therein.

With respect to the Turbin reference, Applicants note that the reference was directed to transfer of a single waxy allele (see page 30, Summary lines 1 and 2). Further, the frequency of altered pollen grains was extremely low according to Turbin et al., with most grains having a wild type phenotype (see page 30, beginning at Summary line 7). Therefore, Turbin et al. does not teach or suggest large scale introgression of donor genes, but rather, Turbin teaches only the introgression of a single allele as a relatively rare event.

Regarding the Christou reference, Applicants note that the only disclosure pertaining to delivery of multiple genes is on page 201 of the reference, in column one. However, a careful reading of this portion of the manuscript reveals that this passage relates to the experiments summarized in Table 2 in the reference, wherein up to three selection marker genes were transferred in a vector construct. Therefore, Christou does not teach or suggest transfer of donor plant nucleic acids in the absence of a vector, wherein 0.01%-10% of the donor plant genome is transferred to the transgenic plant.

Because Turbin et al. teaches that introgression of even a single allele is inconsistent, and because Christou teaches only that multiple genes can be delivered to a

recipient plant by way of a nucleic acid vector, the combination of Turbin and Christou does not provide any suggestion or motivation to arrive at Applicants' invention, as claimed in amended claim 22. Rather, the combination of Turbin and Christou would suggest to the skilled artisan that integration of multiple genes into the genome of a recipient plant would require delivery of donor DNA contained within a vector. In fact, the combination of Turbin and Christou teaches away from the present invention because the Turbin and Christou references, when taken together, suggest that integration of multiple genes into the genome of a recipient plant could be successfully achieved by delivery of donor DNA contained within a vector, but not absent the use of a vector delivery vehicle. Therefore, Applicants submit that the skilled artisan would not have been motivated to combine Turbin and Christou to arrive at the present invention.

Assuming, *arguendo*, that there might have been some motivation for the skilled artisan to combine Turbin and Christou, there would have been no reasonable expectation of success in doing so. That is because, as set forth above, the combination of Turbin and Christou teaches away from the present invention because the Turbin and Christou references, when taken together, suggest that integration of multiple genes into the genome of a recipient plant could be successfully achieved by delivery of donor DNA contained within a vector, but not absent the use of a vector delivery vehicle. Turbin et al. does not teach that successful integration of multiple alleles can be achieved in the absence of the vector delivery vehicles used by Christou.

There was simply no reasonable expectation of success that the combination of these references could arrive at the invention recited in claims 22-25, 27, 28, and 30, as now amended. In fact, the combination of these references illustrates that, prior to Applicants' invention, conventional wisdom had been that plant transformation by microprojectile bombardment was best achieved using one or a few genes inserted into one or more plasmid vectors. This is the teaching of Christou. The deficiencies of Christou, vis a vis the present invention, are not corrected by the teachings of Turbin, which simply teaches a method of using isolated genomic DNA from a cereal crop to transform another cereal crop of the same species. Unlike the teachings of the combined references, the present invention shows, contrary to the expectations of persons of ordinary skill in the art, that microprojectile bombardment of recipient plant tissue with directly isolated DNA (such as high molecular weight plant genomic DNA) in the absence of a vector can stably introduce significant introgressions of genetic material into transgenic plants. As amended, claim 22 (and, therefore, claims 23-25, 27, 28 and 30, which all

ultimately depend from claim 22), requires the selection of at least one transgenic plant having a genome comprising a nucleic acid that corresponds to 0.01% to 10% of a nucleic acid genome of the donor plant. Therefore, there would have been no reasonable expectation of success that the combination of these references would produce the present invention. Thus, the rejection of these claims based on the combination of Turbin and Christou constitutes impermissible hindsight and cannot form the basis for a finding of *prima facie* obviousness under 35 U.S.C. §103(a).

In light of the foregoing arguments, it is clear that the above-identified references do not suggest to, or motivate, one of skill in the art to modify or combine the disclosure of the references to arrive at the present invention. Nor would there have been any reasonable expectation of success in such combination since the combination of these references does not teach or suggest all of the claim limitations as required under 35 U.S.C. §103(a). Therefore, Applicants respectfully request that this obviousness rejection be reconsidered and withdrawn.

The Examiner has also rejected claims 26 and 29 under 35 U.S.C. § 103(a) as being unpatentable over Turbin et al. in view of Christou (1997, *Plant Molecular Biology* 35:197-203), and further in view of Applicants' own admitted statement of the prior art (Xiao et al., 1996, *Nature* 384:223) and Weining et al. (1991, *Theor. Appl. Genet.* 82:209-216). Applicants respectfully traverse this rejection for the following reasons.

It is apparently the Examiner's view that, while Turbin in view of Christou does not teach a donor plant and recipient plant from different genera, Turbin and Christou further in view of Applicants' statement of the prior art in view of Weining et al. (1991, *Theor. Appl. Genet.* 82:209-216) would make it obvious to one of skill in the art that there is "value of producing a rice plant transformed with high molecular [weight] DNA isolated from another species of rice plant."

The Examiner's obviousness rejection of claims 26 and 29 is based upon the view that Turbin et al. teach a method of transforming a barley plant with directly isolated and uncharacterized high molecular weight genomic DNA. This is not the case, as stated clearly in the arguments set forth in the preceding paragraph. Turbin in view of Christou therefore does not arrive at the invention of claims 26 and 29 for the reasons stated in the preceding paragraph where the references are applied to claim 22.

The addition of Xiao and Weining into the combination does not correct the

deficiencies of Turbin and Christou. This is because Xiao and Weining do not teach or suggest the transfer of donor plant nucleic acids in the absence of a vector, wherein 0.01%-10% of the donor plant genome is transferred to a transgenic recipient plant of a different genus than the donor plant, as set forth in claims 26 and 29. Further, the combined teachings do not teach or suggest the selection of at least one transgenic plant having a genome comprising a nucleic acid that corresponds to 0.01% to 10% of a nucleic acid genome of a donor plant of a different genus than the recipient plant. Rather, the Weining reference generally teaches the isolation of native DNA from cereals and grasses, and the Xiao reference teaches that wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield in more common crop species of *Oryzae*.

Accordingly, for all the reasons given above, Applicants respectfully submit that the Examiner has not established a *prima facie* case for the rejection of claim 26 and 29 under 35 U.S.C. § 103(a) and request that the rejection of these claims be reconsidered and withdrawn.

Summary

The amendments made herein are supported in the as-filed specification, and as such, no new matter has been added by way of the present amendment. Applicants respectfully submit that each and every rejection or objection set forth by the Examiner has either been overcome or is now inapplicable, and that the instant application is in full condition for allowance. Favorable examination of the claims on the merits is respectfully requested.

Respectfully submitted,

ROBERT HENRY ET AL.

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By:

Kathryn Doyle
KATHRYN DOYLE, Ph.D., J.D.

Registration No. 36,317
MORGAN, LEWIS & BOCKIUS, LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-4723
Facsimile: (215) 963-5299
E-Mail: kdoyle@morganlewis.com
Attorney for Applicants

KD/TMS

JP